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REMARKS

Claims 1-85 are pending in the application.

The Office Action indicates that claims 2, 8, 17 and 29-85 are withdrawn from consideration. However, in applicant's response to the Restriction Requirement mailed January 16, 2007, Applicants elected the claims of Group I (claims 1-28) with species elections of meningitis B as the antigen and the phospholipid of claim 9 as the phospholipid compound for prosecution on the merits. Claims 1, 3-16 and 18-28 are readable on these species. It is thus respectfully submitted that claim 8 (upon which the phospholipid of claim 9 is readable) has been inadvertently withdrawn in error by the Office.

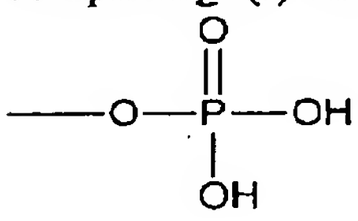
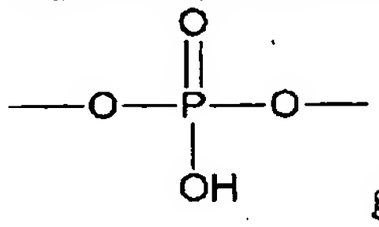
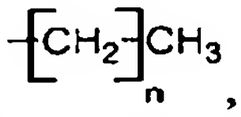
Objection To The Specification – Tables

The Examiner objects to the tables, noting that the titles should appear at the top of each table. The amendments made to the tables above address this objection.

Rejection of Claims 1, 9, 13-15 and 23-38 under 35 U.S.C. §102(a)--Haining

Claims 1, 9, 13-15 and 23-38 are rejected under 35 U.S.C. §102(a) as being anticipated by Haining et al. (Blood, 11/16/02, 100/11: Abstract No. 2648) (Haining). This rejection is respectfully traversed.

To anticipate a claim, a reference must teach every element of the claim. See MPEP 2131 and the references therein. Claim 1, the only independent claim among rejected claims 9, 13-15 and 23-38, reads as follows:

> 1. An immunogenic composition comprising: (a) water; (b) a polymer microparticle comprising a polymer selected from a poly(α-hydroxy acid), a polyhydroxy butyric acid, a polycaprolactone, a polyorthoester, a polyanhydride, and a polycyanoacrylate; (c) an antigen *adsorbed* to the microparticle; and (d) a synthetic phospholipid compound comprising: (i) one or more phosphoryl groups independently selected from a  group and a  group; and (ii) a plurality of linear alkane groups,  , in which n is independently an integer ranging from 6 to 20, or a pharmaceutically acceptable salt thereof.

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In contrast to claim 1, the antigen in Haining is encapsulated in the spray-dried microparticles described therein, rather than adsorbed to the microparticles.

Moreover, the phospholipid described therein, dipalmitoylphosphatidylcholine, is the primary surface tension lowering component of natural lung surfactant (see, e.g., the attached entry no. 2501 from The Merck Index, Thirteenth Edition) and is therefore not synthetic.

For at least the foregoing reasons, claim 1, and claims 9, 13-15 and 23-38 depending therefrom, are patentable over Haining.

Note also that the structure of the phospholipid of rejected claim 9 is remote from that of Haining. For example, R^1 is C(O), leading to a urea-type structure, –NH–C(O) –NH–, at the head of the molecule. Note also that the phospholipid of claim 9 contains six straight chain moieties (R^2, R^3, R^4, R^5, R^6, R^7), each having seven carbon atoms or more, and two of which contain keto moieties (i.e., R^2 and R^5, which are substituted with oxo at the 2 position).

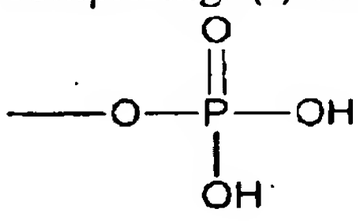
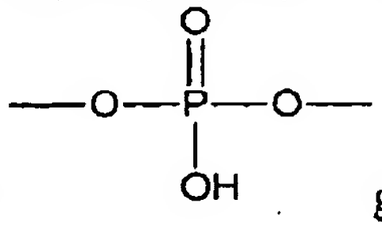
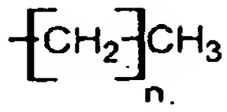
For at least these reasons, reconsideration and withdrawal of the Examiner's rejection are requested.

Rejection of Claims 1, 3-7, 9-19 and 22-28 under 35 U.S.C. §102(b)--Alpar

Claims 1, 3-7, 9-19 and 22-28 are rejected under 35 U.S.C. §102(b) as being anticipated by Alpar et al. WO 00/56282 (Alpar). This rejection is respectfully traversed.

As previously noted, to anticipate a claim, a reference must teach every element of the claim. See MPEP 2131 and the references therein.

Claim 1, the only independent claim among rejected claims 1, 3-7, 9-19 and 22-28, reads as follows:

> 1. An immunogenic composition comprising: (a) water; (b) a polymer microparticle comprising a polymer selected from a poly(α-hydroxy acid), a polyhydroxy butyric acid, a polycaprolactone, a polyorthoester, a polyanhydride, and a polycyanoacrylate; (c) an antigen *adsorbed* to the microparticle; and (d) a synthetic phospholipid compound comprising: (i) one or more phosphoryl groups independently selected from a  group and a  group; and (ii) a plurality of linear alkane groups,  , in which n is independently an integer ranging from 6 to 20, or a pharmaceutically acceptable salt thereof.

In contrast to claim 1, Alpar teaches encapsulation of immunogens (see, e.g., page 3, lines 21-22), rather than adsorbed antigen as claimed.

For at least this reason, claim 1, and claims 3-7, 9-19 and 22-28 depending therefrom, are patentable over Alpar.

Moreover, in contrast to the synthetic phospholipid claimed in claim 1, the phospholipids described in Alpar are of natural origin. Furthermore, the phospholipids described are remote from the specific phospholipid structures of several of the dependent claims (note, for example, the complex branched structures of rejected claims 7 and 9).

For at least these reasons, reconsideration and withdrawal of the Examiner's rejection are requested.

Rejection of Claims 1, 3-7, 9-16 and 18-28 under 35 U.S.C. §103(a)

Claims 1, 3-7, 9-16 and 18-28 are rejected under 35 U.S.C. §103(a) as being unpatentable over Alpar in view of Muttilainen (Microbial Pathogenesis, 1995, 18:423-436) and Cox et al. (Vaccine, 1997, 15/3:248-256). In particular, it is alleged in the Office Action that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Alpar, Muttilainen and Cox et al. with a reasonable expectation of success to prepare the immunogenic compositions as claimed. This rejection is respectfully traversed.

As noted above, Alpar is deficient at least in that (a) Alpar teaches encapsulation of immunogens, rather than adsorbed antigen as claimed, (b) Alpar does not described synthetic phospholipids as claimed. Muttilainen and Cox et al. do not make up for these deficiencies in Alpar.

As indicated in MPEP 706.02(j), a proper rejection under 35 U.S.C. 103 requires, inter alia, an explanation as to why one of ordinary skill in the art at the time the invention was made would have been motivated to make a proposed modification to the prior art to arrive at the claimed subject matter. See also Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co.* v. *Teleflex Inc.*:

> The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting In re Kahn ... stated that " '[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' "

The reasoning articulated in the Office Action does not explain how Muttilainen and Cox et al. make up for the above noted deficiencies in Alpar.

For at least this reason, it is respectfully submitted that claims 1, 3-7, 9-16 and 18-28 are patentable over Alpar, Muttilainen and Cox et al.

CONCLUSION

Applicants submit all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, the Examiner is requested to telephone the Applicant's attorney at (703) 433-0510 in order to resolve any outstanding issues in this case.

FEES

The Office is authorized to charge the additional claims fee as well as any other fees required to deposit account number 50-1047.

Respectfully submitted,

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